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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,101	10/03/2003	Charles Signorino	920-3	2235

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MICHAEL F. PETOCK, ESQUIRE
46 THE COMMONS AT VALLEY FORGE
1220 VALLEY FORGE ROAD, P.O. BOX 856
VALLEY FORGE, PA 19482

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,101	SIGNORINO ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by "diacetylated monoglyceride" in claim 1. If it is diactylated, then it will be a diglyceride or just glycerol. Further clarification is requested.

Claims 20-21 are directed to "method in accordance to claim 19; however claim 19, directed to an emulsion. Therefore, it is unclear if applicant attempting to claim a method of preparing the composition since claims 20-21 do not actually specify what the method is and dependent claims 20-21 depend on a composition claim and thus do not limit the subject matter of the parent. For the purposes of applying prior art, the examiner will treat the claims as product-by-process limitations since they depend on a composition claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-7, 14-15, 17-18, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yiv (6,245,349).

Yiv discloses microemulsions containing a vegetable oil (0.5 to 50 %), 3-50% surfactant, specifically polysorbate 80 (Tween 80), 3-50% propylene glycol or glycerol. The particle sizes are less than 50 microns See abstract, col. 2, lines 20-64; col. 5, line 2-16., col. 6, lines 14-62; examples and claims.

Regarding claim 6-7, Yiv discloses the instant emulsion; thus it is the examiner's position that the emulsion will have the claimed properties since "Products of identical chemical composition can not have mutually exclusive properties." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding claims 17 and 18, these claims recite the claim language "which is adaptable" and "which is adapted" respectively. The examiner directs applicant's attention is directed to MPEP 2106 II (C), "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." Further, the limitations following the optional language is intended use limitations (adaptable to be stirred), which is not given patentable weight and does not limit the emulsion itself.

Regarding claims 19, which claims an emulsion comprising a water insoluble lipophile, the examiner directs applicant's attention to MPEP section 2113 regarding the process-by-process limitations, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process

claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Regarding claims 20-21 and in light of the 112, second paragraph rejection, the above discussion of product-by-process applies.

Claims 1-7, 9, 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wretlind (4,073,943).

Example 7 discloses a microemulsion comprising 10% soybean oil and 0.36% Tween 80 (poysorbate 80), 2.5% glycerol, and water. The particles formed after dispersion in water have a size of less than 1 micron. See claim 1 and abstract.

Regarding claim 6-7, Wretlind discloses the instant emulsion; thus it is the examiner's position that the emulsion will have the claimed properties since "Products of identical chemical composition can not have mutually exclusive properties." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding claim 9, Tween 80 is used in an amount of 3.6% of the soybean oil, which reads on "about 2%" since applicant has not defined the term "about" to mean exactly. See MPEP 2111.01 IV.

Regarding claims 17 and 18, these claims recite the claim language "which is adaptable" and "which is adapted" respectively. The examiner directs applicant's attention is directed to MPEP 2106 II (C), "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." Further, the limitations following the optional language is intended use

limitations (adaptable to be stirred), which is not given patentable weight and does not limit the emulsion itself.

Regarding claims 19, which claims an emulsion comprising a water insoluble lipophile, the examiner directs applicant's attention to MPEP section 2113 regarding the process-by-process limitations, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Regarding claims 20-21 and in light of the 112, second paragraph rejection, the above discussion of product-by-process applies.

Claims 1-3, 6-7, 9, 14, 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rudnic et al (5,952,004).

Rudnic discloses an emulsified drug delivery system. The emulsion comprises a hydrophobic phase such as glyceryl monostearate and 0.05-50% and preferably 1-3% of a surfactant. see column 5, lines 30-35. The composition is in the form of a microemulsion wherein the droplet sizes are approximately 200 A. see column 3, lines 1-5 and column 6, lines 20-40. Example 1 discloses a composition comprising 5-60% glyceryl monostearate, 5% polysorbate 80, and water. The oil-in-water emulsions of the invention are generally made by adding hot (70-80.degree. C.) hydrophobic phase (smaller by weight) to hot (70-80.degree. C.) hydrophilic phase (larger by weight) forcing inversion of the surface-active agent to form a

disperse emulsion of unaggregated dispersed phase particles. Example 1 teaches the ingredients of each phase are heated separately to 70-80.degree. C. Phase B is added to phase A while mixing in an appropriate mixing device. The mixture is then cooled to room temperature.

Regarding claims 3 and 9, note that GMS is disclosed in a maximum amount of 50% and the surfactant in a minimum amount of 1%; thus the amount of the surfactant to lipophile is 2%.

Regarding claim 6-7, Rudnic discloses the instant emulsion; thus it is the examiner's position that the emulsion will have the claimed properties since "Products of identical chemical composition can not have mutually exclusive properties." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Regarding claims 17 and 18, these claims recite the claim language "which is adaptable" and "which is adapted" respectively. The examiner directs applicant's attention is directed to MPEP 2106 II (C), "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." Further, the limitations following the optional language is intended use limitations (adaptable to be stirred), which is not given patentable weight and does not limit the emulsion itself.

Regarding claims 19, which claims an emulsion comprising a water insoluble lipophile, the examiner directs applicant's attention to MPEP section 2113 regarding the process-by-process limitations, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even

though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Regarding claims 20-21 and in light of the 112, second paragraph rejection, the above discussion of product-by-process applies.

Claims 1-2, 4-7 and 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Petereit et al, (Eur. J. Pharm. Biopharm, 1995) of record.

Petereit et al disclose emulsion formulations containing glyceryl monostearate, polysorbate 80, triethyl citrate and water. The emulsions further contain 10% PEG. (Table 9) Table 4 teaches the suspension comprises 4.5% GMS. 0.4% Tween 80, and water. The instant amount of plasticizer is disclosed. The micelle sizes are less than 1 micron and compatible with acrylate copolymers (pages 224 and abstract). Petereit discloses the method of preparing generally comprises dispersing GMS above 60 degrees or at room temperature with intensive dispersers. See page 227. On page 220, the reference teaches water, polysorbate 80, GMS, and plasticizer are added to a beaker and heated up to 65 degrees C and homogenizing for 15 minutes using an Ultra Turrax. The suspension is cooled. See page 221.

Regarding claims 19, which claims an emulsion comprising a water insoluble lipophile, the examiner directs applicant's attention to MPEP section 2113 regarding the process-by-process limitations, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even

though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Regarding claims 20-21 and in light of the 112, second paragraph rejection, the above discussion of product-by-process applies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-13 [redacted]der 35 U.S.C. 103(a) as being unpatentable over Petereit et al, (Eur. J. Pharm [redacted] 995).

Petereit et al [redacted] bove, teach emulsion formulations containing glyceryl monostearate, polysorbate 80, triethyl citrate or PEG and water. Different weight percents of the GMS, polysorbate 80, and plasticizer are taught in Table 4 and 9.

Petereit et al do not teach all of the claimed amounts or ranges for the lipophilic agent, stabilizer and the plasticizer.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Petereit et al and manipulate the amounts of the components. One would have been motivated to do so with a reasonable expectation of success and similar results since Petereit teaches using various amounts of each component and teaches the amount of polysorbate 80 reduces the particle size and improves the process; while the plasticizer is used as needed; and GMS is used in an amount of 2-20% (See

page 222). Therefore, it would have been obvious to experiment within these given range during routine optimization. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 10 is r[redacted]35 U.S.C. 103(a) as being unpatentable over Rudnic et al (5,952,004).

The teachings [redacted]e been set forth above. Rudnic teaches the use of 5-60% GMS and 0.05-50% and preferably 1-3% of a surfactant. The oil-in-water emulsions of the invention are generally made by adding hot (70-80.degree. C.) hydrophobic phase (smaller by weight) to hot (70-80.degree. C.) hydrophilic phase (larger by weight) forcing inversion of the surface-active agent to form a disperse emulsion of unaggregated dispersed phase particles. This produces an emulsion when processed under suitable shear. Common equipment include propeller or turbine mixers, homogenizers, colloid mills, ultrasonic mixers and microfluidizers. Examples of such brand name mixing equipment are Lee Kettle, Gaulin mixer and Stephan. The shear of the agitation should be sufficient to form a stable dispersion, but not too great to cause degradation of the drug. See column 6, lines 20-40. Example 1 teaches the ingredients of each phase are heated separately to 70-80.degree. C. Phase B is added to phase A while mixing in an appropriate mixing device. The mixture is then cooled to room temperature.

Rudnic et al do not teach all of the claimed amounts or ranges for the lipophilic agent and stabilizer.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Rudnic et al and manipulate the amounts of the components. One would have been motivated to do so with a reasonable expectation of success and similar results since Rudnic teaches the general ranges of each components, i.e. 0.05-50% and preferably 1-3% of Tween 80 and 5-60% GMS. Therefore, it would have been obvious to experiment within these given range during routine optimization. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 11/163735. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Primary Examiner
Art Unit 1616

SSG